

K053065

JAN 3 2006

510(k) Summary
Full Breath Sleep Appliance – PB (Posterior Bite)
Full Breath Sleep Appliance – PBB (Posterior Bite with Bumps)

Applicant

Bryan Keropian DDS
18607 Ventura Blvd., Suite 206
Tarzana, CA 91356

Product Name

Full Breath Sleep Appliance – PB (Posterior Bite)
Full Breath Sleep Appliance – PBB (Posterior Bite with Bumps)

Proposed Product Code

LQZ

Proposed Device Classification

Jaw Repositioning Device

Contact Person

Bryan Keropian DDS
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510(k) Application Preparation

Bryan Keropian, DDS

510(K) Summary (continued)

This is a simple enhancement to the design of the Quiet Night & Quiet Night MA (K032410). It incorporates the Quiet Night function of control of vertical dimension and mandibular advancement for reduction/elimination of snoring. It also incorporates the posterior trans-palatal bar of the Quiet Night and Quiet Night MA to prevent the tongue from sealing against the palate and thus reduce snoring. It also restrains the tongue from up and back movement. The tongue restraint has resulted in reduced AHI/RDI's, and elevation of the O2 low saturation (nadir) when sleeping.

DEVICE SPECIFICATIONS

The Full Breath Sleep Appliance PB & PBB is a custom device fabricated typically by a Professional dental laboratory and delivered by a dentist.

<u>Product Name</u>	<u>Full Breath Sleep Appl.</u>	<u>Quiet Night Quiet Nt. MA</u>	<u>Breathe EZ Anti-Snoring Device</u>	<u>Sleepbite</u>	<u>The Silencer</u>
510(k)	Pending	K032410	K022891	K103808	K954530
<u>Product Code</u>	<u>LQZ</u>	<u>LQZ</u>	<u>LRK</u>	<u>LRK</u>	<u>LRK</u>
<u>Indicated Use</u>	Treatment of Mild & Mod. OSA	Treatment of Mile & Mod OSA	Treatment of Snoring	Treatment of Snoring	Treatment of Mild & Mod OSA
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	Treatment of Snoring	Treatment of Snoring	Treatment of Snoring	Treatment of Snoring	Treatment of Snoring
<u>Method of Delivery</u>	By prescription	By prescription	By prescription	By prescription	By prescription

INDICATIONS FOR USE

1. An oral appliance to be used for the treatment of mild and moderate Obstructive Sleep Apnea.
2. For the treatment of snoring.
3. For the prevention of bruxism.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 3 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Bryan Keropian
18607 Ventura Boulevard, Suite 206
Tarzana, California 91356

Re: K053065

Trade/Device Name: Full Breath Sleep Appliance – PB (Posterior Bite)

Full Breath Sleep Appliance – PBB (Posterior Bite with Bump)

Regulation Number: 21 CFR 872.5570

Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring
and Obstructive Sleep Apnea

Regulatory Class: II

Product Code: LQZ

Dated: October 31, 2005

Received: November 1, 2005

Dear Dr. Keropian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

S10(k) Number (if known): K 053 065

Device Name: Full Breath Sleep Appliance - PB (Posterior Bite)
Full Breath Sleep Appliance - PBB (Posterior Bite with Bumps)

Indications for Use:

- ns for Use:
- 1) AN ORAL APPLIANCE TO BE USED FOR THE TREATMENT OF MILD AND MODERATE OBSTRUCTIVE SLEEP APNEA
 - 2) FOR THE TREATMENT OF SNORING.
 - 3) FOR THE PREVENTION OF BRUXISM.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Office of Device Evaluation

Med. General Hospital,
Las Vegas